

JUN 21 2001

510(k) SUMMARY

A. Submitter Information:

Submitter: MEDCOMP®
1499 Delp Drive
Harleysville, PA 19438
(215) 256-4201 Telephone
(215) 256-0818 Fax

Establishment Registration #: 2518902

Contact: Jeanne M. Cush
Senior Regulatory Affairs Associate

Date Prepared: May 14, 2001

B. Special 510(k) Corrective Action Being Affected

Product Affected: Medcomp Ash Split- Cath K972207
Product Modification: Addition of Safety Slide Clamp
Classification: 78 MSD
C.F.R. Section: 876.5540

C. Description of Device Modification:

Medcomp has received (5) complaints (June 2000) concerning extension clamps. All the complainants reported the clamp was not occluding the extension tube, or occludes the extension tube intermittently. The clamps are intended to occlude the extensions and prevent blood loss between dialysis treatments. Though injection caps taped to the luer connectors serve as a backup for blood loss between treatments, relying on the backup system increases the risk of accidental blood loss.

Medcomp confirmed the complaints and determined the root cause is use of Halkey-Roberts clamps manufactured from their new hot molding process.

Medcomp has determined that to prevent possible leakage in the field, a safety slide clamp would be provided for installation on the suspect catheters in the field. These safety slide clamps were provided to all dialysis units and affected hospitals as a preventive measure.

Medcomp selected a standard "off the shelf" slide clamp designed to pinch or occlude a variety of medical tubing. This slide clamp is widely used throughout the medical device industry to prevent air or fluid communication. Medcomp clamp specification is included in Section 4.

This submission contains the following documentation associated with the Product Correction:

- Correction Report 2518902-10/12/00-001-C
- Product Correction Notification (September 27, 2000)
- Safety Slide Clamp Instructions for Installation
- Performance Data (Simulated Use Testing V-1026)

Although this corrective action has already been implemented to prevent the surgical removal of implanted hemodialysis catheters, this submission is required in accordance with K95-1 Memorandum "510(k) Requirements for Proposed Fixes to Devices Undergoing Recall.

To date, only 1 complaint has been received concerning the failure of the safety slide clamp. The complaint stated that the extension tube was damaged by repeated application of the slide clamp. We have been unable to replicate this alleged failure, and this failure mode did not occur during the 52-week simulated use testing included in Section 5 of this submission. We therefore conclude that the retrofit of the safety slide clamp proves to be a safe and effective correction for implanted catheters in which the Halkey Roberts clamps do not fully occlude the extension tube.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 21 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jean M. Cush
Senior Regulatory Affairs Associate
MEDCOMP®, Inc.
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K011576
Addition of Safety Slide Clamp to
MEDCOMP® Ash Split-Cath, Duo-FlowXL,
and Duo-Split Catheters
Dated: May 16, 2001
Received: May 22, 2001
Regulatory Class: II
21 CFR §876.5540/Procode: 78 NFK

Dear Ms. Cush:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE

510(k) Number: K011576

Device Name: Medcomp Safety Slide Clamp

Indications for use:

The Medcomp Safety Slide Clamp is intended to provide a secondary extension tube clamp on the Medcomp Ash Split-Cath, Duo-Flow 400XL and Duo-Split Catheters to prevent leakage during connection or disconnection of the bloodlines.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter

(Optional Format 1-2-96)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011576